REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 1-26, 30, 32-37, 39 and 40 were pending in this application when last examined.

Claims 30, 32-37, 39 and 40 were examined on the merits and stand rejected.

Claims 1-26 were withdrawn as non-elected subject matter.

Claims 30 and 37 are amended. The basis for "encoding a protein having an amino acid sequence represented by SEQ ID NO: 4" in claim 30 is in the specification page 26, line 22 to page 27, line 7. The basis for the "pharmacological target of a protein encoded by the DNA is cancer tissue and not the cell" in claim 30 is in the specification on page 1, lines 9-13 and page 6, lines 20-24.

Claim 37 is amended in light of the amendments to claim 30.

No new matter has been added.

II. ENABLEMENT REJECTION

On pages 3-5 of the Office Action, claims 32-37 and 39-40 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification is only enabling for a method of inhibiting growth, invasion and metastasis of cancer or for inhibiting angiogenesis, which comprises administering a cell containing preparation comprising a cell which has a DNA as set forth in SEQ ID NO: 2, which encodes a mature human NK4 polypeptide, and not for other fragments or variants thereof which encode a protein which has an activity equivalent to NK4.

Applicants respectfully traverse this rejection as applied to the amended claims. In particular, it is noted that claim 30, without acquiescence to the correctness of the Examiner's position, has been amended to remove that which was considered non-enabled by the Examiner.

Thus, this rejection is overcome.

III. OBVIOUSNESS REJECTIONS

On pages 5-9 of the Office Action, claims 30, 32 and 34-37 and 39 were rejected under 35 U.S.C. § 103(a) as obvious over Folkman et al. (US 6,024,688) in view of Kuba et al. (Cancer

Res., 2000), Nakamura (EP 1074264), Nakamura (WO 99/55361) and Seki et al. (Biochem. Biophys. Res. Commun., 1990).

Further, on page 9, claim 33 was rejected under 35 U.S.C. § 103(a) as obvious over Folkman et al. (US 6,024,688) in view of Kuba et al. (Cancer Res., 2000), Nakamura (EP 1074264), Nakamura (WO 99/55361) and Seki et al. (Biochem. Biophys. Res. Commun., 1990) and further in view of Allen et al. (US 7,115,256).

Finally, on pages 9-10, claims 30 and 40 were rejected under 35 U.S.C. § 103(a) as obvious over Folkman et al. (US 6,024,688) in view of Kuba et al. (Cancer Res., 2000), Nakamura (EP 1074264), Nakamura (WO 99/55361) and Seki et al. (Biochem. Biophys. Res. Commun., 1990) and further in view of Medico et al. (US 6,551,991) and Junqueira et al. (Basic Histology, 1986).

Applicants respectfully traverse these rejections as applied to the amended claims.

The essential features of the invention of amended claims 30 are as follows:

(1) The cell has a DNA having a base sequence represented by SEQ ID NO: 2 (i.e. NK4 gene) or a DNA encoding a protein having an amino acid sequence represented by SEQ ID NO: 4 (i.e. NK4 protein).

(2) The pharmacological target of a protein encoded by the DNA is cancer tissue and not the cell.

(3) The cell-containing preparation comprises a mesh sheet comprising a biodegradable resin.

(1) NK4 is structurally and patentably distinct from angiostatin

Regarding characterization (1), the Examiner states in the first office communication that it would have been obvious to one of skill in the art to have used a DNA encoding the human HGF/NK4(del5) of Nakamura as the anti-angiogenic factor in the cell method of Folkman, because Kuba teaches that human NK4 is structurally and functionally very similar to angiostatin exemplified by Folkman and is anti-angiogenic polypeptide.

However, Kuba teaches that the amino acid sequence homology between four kringles of NK4 and angiostatin reaches 47% (lines 11-15 on the left column of page 6742). Therefore, homology between full-length NK4 and angiostatin should be lower than 47%. Thus, NK4 is structurally and patentably distinct from angiostatin.

Accordingly, it would not have been obvious to one of skill in the art to replace angiostatin with NK4 in the cancer-treating method of Folkman.

(2) Target of NK4 in the present invention is not the cells

Regarding characterization (2), Medico teaches that epithelial cells can be a target of HGF (lines 10-15 on the right column 2). This means that epithelial cells would also be target of NK4, since NK4 is an antagonist of HGF.

However, in the claimed invention, NK4 secreted from epithelial cells do not stay there and move to the target cancer cells. In a sharp contrast with above anticipation through Medico, according to the present invention, the target of NK4 is cancer cells and not epithelial cells. This is quite surprising and unexpected to those skilled in the art.

In fact, according to the Office's position, a person of skill in the art would not be motivated to practice the claimed invention if NK4 and HGF were equivalent. In other words, a person of skill in the art would not use the claimed cell preparation to treat cancer or inhibit angiogenesis as such skilled artisan would expect that NK4 would merely target the cells contained in the claimed preparation.

(3) The present invention includes mesh sheet

Regarding characterization (3), none of the cited references teach or suggest that a biodegradable resin is formed into a mesh sheet. The Examiner neglects this point. It is noted that for obviousness, every claim limitation must be shown to be taught or suggested.

As a result, the inventions of claims 30, and 32-37 and 39-40 depending on claim 30, are unobvious from the cited references.

Thus, Applicants respectfully suggest that these rejections are untenable and should be withdrawn.

IV. CLAIM OBJECTION

On page 11 of the Office Action, claim 37 was objected to for being a duplicate of claim 30. This rejection is overcome, as applied to amended claim 37 in light of amended claim 30, for reasons which are self-evident.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

Takehisa MATSUDA et al.

/William R. Schmidt, II/

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